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VIA FACSIMILE

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Dear Mr. Gibbs:

This responds to your letters concerning Applied Digital Solutions (ADS)'s two separate written requests submitted to the Center for Devices and Radiological Health (CDRH or the Center) under Section 513(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requesting a determination that the VeriChip is not a medical device under the FD&C Act for the intended uses described in the requests. Your requests cover two different intended uses of the product. The first is for use of the VeriChip in health information applications ("health information VeriChip"). The second is for security, financial, and personal identification\safety applications ("personal ID\security VeriChip"). For the reasons discussed below, FDA believes that the health information VeriChip is a medical device subject to FDA's jurisdiction. FDA agrees, however, that the personal ID/security VeriChip is not covered by the FD&C Act.

Background

Since 1986, Digital Angel Corporation, which is working with VeriChip Corporation, has sold more than 20 million implantable RFID transponders for animals, including companion animals such as dogs and cats; livestock animals such as pigs and cattle; fish and a variety of other species. VeriChip is one of those same chips, with the same internal components, the same glass envelope, and a slightly revised number system. The transponders provide access to information necessary to identify the animal.

In January of 1984, the Center for Veterinary Medicine (CVM) within FDA issued a letter to the manufacturer of this product stating: "This product is a microminiature transponder that is embedded in non-reactive plastic and may be inserted by hypodermic needle into animals of all sizes. The device does not have a medical\therapeutic function. Therefore, we have no objection to marketing of this identification device for use in animals."

In 1986, FDA again wrote the company stating:

> "This is in response to your March 21, and July 8, 1986 letters concerning the status of your product 'System I.D.' with the use of R6 Soda Lime glass for encapsulation rather than non-reactive plastic as originally proposed. . . . "
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> "This product is a microminiature transponder inserted by hypodermic needle into animals of all sizes. The device does not have a medical\therapeutic function. That has not changed by the use of glass for encapsulating instead of plastic. Therefore, we have no objection to marketing of this device for use in animals."

ADS has determined to market in the United States a version of the microminiature transponder, known by the trade name "VeriChip," for a variety of uses in human beings. We understand from ADS that the VeriChip is a microminiature transponder that is encapsulated in medical grade glass that may be inserted by hypodermic needle under the skin of the upper arm in humans. The chip\transponder stores a unique identification number only. A small, handheld introducer is used to place the chip subcutaneously. A small, handheld battery-powered scanner can read the identification number on the chip. That number enables access to a database providing individual identity and access rights to information or facilities. The personal ID\security VeriChip would allow access, via the database, to information related to security, financial, and personal safety applications only. You have represented that it will not contain any medical information. By contrast, ADS and its representatives have explained, the health information VeriChip would allow access, via the database, to medical history and other information to assist medical personnel in diagnosing or treating an injury or illness.

Regulatory Status of the VeriChip

We believe that the health information product, which facilitates access to information for use by medical professionals in treating the individual with the VeriChip embedded in his or her arm, is "intended for use in the diagnosis of disease or other conditions, or in the cure [or] mitigation of disease." The information in the database is meant to be used by medical professionals in diagnosing a disease or other condition. Indeed, the entire purpose of this product is for a medical professional to employ when treating a stricken individual. For example, information about whether the person is allergic to a particular medicine, or has an implanted pacemaker, which is accessed in connection with the VeriChip, is intended for use in treating the person. Accordingly, FDA has determined that the health information VeriChip is a medical device within the meaning of Section 201(h)(2) of the FD&C Act.[1]

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[1] The health information VeriChip does not meet any of the three broad categories of computer products not subject to regulation as a medical device. It is not used for a traditional library function, it is not used as a general

By contrast, as CVM recognized with respect to the use of the VeriChip predecessor in animals, it does not appear that the personal ID/security VeriChip is a medical device, even though it is an "implant." It is of course true that virtually any product that comes into contact with the body—and many that do not—could be said to have an effect on the structure or a function of the body. However, as you note in your Section 513(g) submission, FDA's medical device jurisdiction under Section 201(h)(2) extends only to such products that are marketed by their manufacturers or distributors with claims of effects on the structure or a function of the body. In the language of the statute itself, the product must be "intended to" affect the structure or a function of the body. It is well settled that intended use is determined with reference to marketing claims.

As early as Bradley v. United States, 264 F. 79 (5th Cir. 1920), courts were finding "intended use" based upon marketing claims. In 1953, the Second Circuit held that claims are essential to establish an "intended use." FTC v. Liggett & Myers Tobacco Co., 203 F.2d 955 (2d Cir. 1953) (per curiam), aff'g 108 F. Supp. 573 (S.D.N.Y. 1952). "The real test is how . . . this product [is] being sold[.]" United States v. Nutrition Serv., Inc., 227 F. Supp. 375, 386 (W.D. Pa. 1964), aff'd, 347 F.2d 233 (3d Cir. 1965). The courts "have always read the . . . statutory definitions employing the term 'intended' to refer to specific marketing representations." American Health Prods. Co. v. Hayes, 574 F. Supp. 1498, 1505 (S.D.N.Y. 83) (citations omitted), aff'd on other grounds, 744 F.2d 912 (2d Cir. 1984). This is what has traditionally been understood as "objective intent." 21 C.F.R. §§ 201.128 & 801.4.

Indeed, just four years ago, the United States Court of Appeals for the Fourth Circuit found that "no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [FD&C Act] absent manufacturer claims as to that product's use." Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 163 (4th Cir. 1998) (internal quotation marks omitted) (citing Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1390 (M.D.N.C. 1997)), aff'd, 529 U.S. 120 (2000); see also United States v. Undetermined Quantities . . . "Pets Smellfree," 22 F.3d 235, 240 (10th Cir. 1994) ("PSF's claims [in labeling and promotional materials] . . . bring Smellfree within the scope of § 321(g)(1)(C)."); United States v. Storage Spaces Designated Nos. "8" and "49," 777 F.2d 1363, 1367 n.6 (9th Cir. 1985) (relying on "the manner in which the products [were] promoted and advertised" in finding that the products were drugs under Section 321(g)(1)(C)); United States v. An Article of Device . . . Amblyo-Syntonizer, 261 F. Supp. 243, 244 (D. Neb. 1966) (articles were sold to "only those optometrists who take courses [from the distributor] concerning the purpose and use of the device").

In a 1994 case, FDA stated that it "does not claim that a device which has no medical application could 'qualify as a device under the FD&CA.'" United States v. Undetermined

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counting or communications function, and it is not solely for educational purposes. FDA Policy for the Regulation of Computer Products (November 13, 1989) (emphasis added).

Number of Unlabeled Cases, 21 F.3d 1026, 1030 (10th Cir. 1994) (Cook, J., concurring in part and dissenting in part) (quoting Brief for the United States at 16) (emphasis added).[2] Courts have held that Section 201(h)(3) only encompasses products claimed to affect the body "in some medical—or drug-type fashion, i.e., in some way other than merely altering the appearance." An Article . . . "Sudden Change," 409 F.2d at 742 (internal quotation marks omitted) (emphasis added). See E.R. Squibb & Sons, Inc. v. Bowen, 870 F.2d 678, 682-83 (D.C. Cir. 1989) (Section 201(h)(3) is interpreted to be "relatively narrow.").

The pertinent legislative history supports this interpretation. Specifically, the Senate Report accompanying the legislation that became the Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938), states:

> The use to which the product is to be put will determine the category into which it will fall. . . . The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put.

S. Rep. No. 74-361, at 240 (1935) (emphasis added); see also Foods, Drugs, and Cosmetics: Hearings on S. 2800 Before the Sen. Comm. on Commerce, 73d Cong. 517-18 (1934) (a table would be subject to FDA jurisdiction only if claimed to have medical application). As the D.C. Circuit found, that intended use is determined by manufacturer marketing claims "has now been accepted as a matter of statutory interpretation" by the federal courts. Action on Smoking and Health v. Harris, 655 F.2d 236, 238-39 (D.C. Cir. 1980).

Accordingly, assuming that no medical claims are made for the personal ID\security VeriChip, and the product marketed for that purpose contains no health information, FDA can confirm that it is not a medical device.

It is, of course, foreseeable that any implant, such as the personal ID\security VeriChip, will have an effect on the structure and function of the body; indeed, it will be permanently embedded under a person's skin. However, as the Fourth Circuit recently held, a foreseeable effect on the structure or function of the body does not establish an intended use. Sigma-Tau Pharmaceuticals, Inc. v. Schwetz, 288 F.3d 141 (4th Cir. 2002) (rejecting the contention that under 21 C.F.R. § 201.128, FDA must consider evidence of likely post-approval use), aff'g 2001 U.S. Dist. LEXIS 11247 (D. Md. Aug. 3, 2001). If the foreseeability theory had been accepted by the courts, FDA would have won several cases that it lost. See, e.g., United States v. Articles of Drug for Veterinary Use, 50 F.3d 497 (8th Cir. 1995); National Nutritional

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[2] Indeed, as a 1937 Report from the House Interstate and Foreign Commerce Committee noted, "[s]peaking generally, 'devices' within the terms of the act means instruments and contrivances intended for use in the cure or treatment of disease. 'Devices' are included within the bill because of their close association with drugs as a means for the treatment of physical ills." H.R. Rep. No. 75-1613, at 2.

Foods Ass'n v. Mathews, 557 F.2d 325 (2d Cir. 1977); National Nutritional Foods Ass'n v. FDA, 504 F.2d 761 (2d Cir. 1974).

Also, if foreseeability were a permissible basis for finding an intended use as that term is used in Section 201(h)(3), FDA's jurisdiction would encompass many articles having foreseeable physical effects. Yet FDA only regulates products if they are marketed with claims of medical or therapeutic utility. For example, FDA only regulates exercise equipment as a medical device when it is marketed with claims to prevent, treat, or rehabilitate injury or disability. Otherwise, it is a consumer product. See Letter from Thomas Scarlett to James V. Lacy (May 6, 1988); 21 C.F.R. §§ 890.5350-890.5380; see also Pillow Used To Aid Sleep or Rest (Mother's Pillow)—Device Status (updated Jan. 31, 2002) (available at <www.fda.gov/cdrh/devadvice/21aaa.html>); Sun Protective Fabrics/Articles of Clothing (updated Apr. 15, 1998) ("FDA has decided that it is not the appropriate agency to regulate SPC [(sun protective clothing)] for which no medical claims are made and which are only intended for general use.") (available at <www.fda.gov/cdrh/devadvice/21a.html>); Letter from Richard M. Cooper, Chief Counsel, FDA to Stephen Lemberg, Ass't Gen. Counsel, CPSC (May 14, 1979) (available at <http://www.cpsc.gov/library/foia/advisory/276.pdf>) (electrostatic air cleaners).

In addition, if foreseeable effects were cognizable under Section 201(h)(3), FDA's legal authority would intrude into consumer product regulation—an area of responsibility delegated by Congress to another federal agency. CPSC's jurisdiction extends to "consumer products," which means "any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise . . . ." 15 U.S.C. § 2052(a)(1). The definition expressly excludes "drugs, devices, or cosmetics (as such terms are defined in sections 201(g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act . . .)." Id. § 2052(a)(1)(H).

Similarly, if Section 201(h)(3) of the FD&C Act were interpreted to give FDA jurisdiction over any product foreseeably having an effect on the structure or a function of the body, then regulatory authority would shift from the CPSC to FDA for a host of non-health-related products. Hiking boots; shirts, pants, and coats; exercise equipment; insulated gloves; airbags; and chemical sprays can be said to affect bodily structure or function. Clothing and gloves, for example, keep the body warm. It is for this reason that FDA's regulations discuss objective, as opposed to subjective, intent. 21 C.F.R. §§ 201.128 & 801.4. Foreseeability by the manufacturer does not suffice to establish intended use. Rather, there must be "objective intent" in the form of marketing claims.

Moreover, for FDA to treat as "intended" every foreseeable effect on the structure or a function of the body would subject off-label use to unintended regulation. Off-label use of

medical products is ubiquitous, often comprising the standard of care. See, e.g., Janet Woodcock, A Shift in the Regulatory Approach, 32 Drug Info. J. 367, 367 (1998); GAO, Report to the Chairman, Sen. Comm. on Labor and Human Resources: Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies 19 (Sept. 1991).[3] Given that many off-label uses are foreseeable, for FDA to require pre-approval for every use of a product made in the absence of claims would dramatically harm the public health. As one court put it,

> New uses for drugs are often discovered after FDA approves the package inserts that explain a drug's approved uses. Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming process of obtaining FDA approval before putting drugs to new uses.

United States v. Algon Chem. Inc., 879 F.2d 1154, 1163 (3rd Cir. 1989) (quoting Chaney v. Heckler, 718 F.2d 1174, 1180 (D.C. Cir. 1983), rev'd on other grounds, 470 U.S. 821 (1985)).

Finally, adoption of a foreseeability theory of intended use would undermine the generic drug approval process. The abbreviated new drug approval (ANDA) process, created by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585, provides for FDA approval of a generic drug based on a showing of bioequivalence to the innovator counterpart. Approval is authorized only if the generic drug's labeling is substantially identical to the labeling for the innovator. 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. § 314.94(a)(3). Because the medical community's experience with an innovator product following approval frequently reveals clinically useful off-label uses, by the time the generic version is approved it is likely to have foreseeable uses that its innovator predecessor did not have. If foreseeable use constituted intended use, then FDA would lack authority to approve a generic drug because all foreseeable uses would have to be in the labeling, and the additional uses would cause the generic labeling to differ from the innovator labeling. The generic drug manufacturer could only obtain approval of the new indications by developing the clinical and other data required in a full NDA. Interpreting "intended use" to include foreseeable use would thus utterly defeat the purposes of the generic drug legislation, with ill effects for the cost and availability of drugs.

Conclusion

[3] According to a 1991 report of the General Accounting Office, 33 percent of all drugs being administered to treat cancer were being prescribed "off label," and 56 percent of the cancer patients surveyed were given at least one drug for an unapproved use. GAO, Report to the Chairman, Sen. Comm. on Labor and Human Resources: Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies 19 (Sept. 1991).

For the reasons set forth above, FDA has determined that the VeriChip, when marketed to provide information to assist in the diagnosis or treatment of injury or illness, is a medical device. CDRH will be in touch with you shortly as to what its expectations are with respect to that product. In the meantime, we expect that you will not market that product. So long as no medical claims are made for the personal ID\security VeriChip, FDA can confirm that it is not a medical device.

Please do not hesitate to contact us if you have any questions or wish to discuss this matter further.

Sincerely,

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